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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,974

03/02/2006

Toshiyuki Takagi

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26389 7590 06/27/2007  
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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

06/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/554,974	Applicant(s) TAKAGI ET AL.	
	Examiner Kevin E. Weddington	Art Unit 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005 and 02 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 13-30 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The preliminary amendments filed October 28, 2005 and March 2, 2006 have been received and entered.

Due to the complex nature of the claims, no request for an oral election is being made. Please see MPEP 812.01.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 13, 15-18, 25, 27 and 28 are drawn to a method for enhancing glucose uptake into warm-blooded animal cells comprising administering to a warm-blooded in need thereof an effective amount of one or more HMG-CoA reductase inhibitor(s), classified in class 514, subclass 423.
- II. Claims 14-18, 25, 27 and 28 are drawn to a method for enhancing glucose uptake into warm-blooded animal cells in the presence of insulin comprising administering to a warm-blooded in need thereof an effective amount of one or more HMG-CoA reductase inhibitor(s), classified in class 514, subclasses 3 and 423.
- III. Claims 19-21, 23-26, 29 and 30 are drawn to a method for the treatment of diabetes, hyperglycemia, glucose intolerance or gestational diabetes mellitus, or the treatment or prophylaxis of diabetic complications in a warm-blooded animal comprising administering to a warm-blooded animal in need of such treatment an effective amount of one or more medicament(s) selected from the group consisting of pravastatin,

Art Unit: 1614

lovastatin, simvastatin, fluvastatin, cerivastatin, atorvastatin, pitavastatin and rosuvastatin, classified in class 514, subclasses 423 and 866.

- IV. Claims 20, 22-26, 29 and 30 are drawn to a method for the treatment of diabetes, hyperglycemia, glucose intolerance or gestational diabetes mellitus, or the treatment or prophylaxis of diabetic complications in a warm-blooded animal caused by insulin resistance syndrome comprising administering to a warm-blooded animal in need of such treatment an effective amount of one or more medicament(s) selected from the group consisting of pravastatin, lovastatin, simvastatin, fluvastatin, cerivastatin, atorvastatin, pitavastatin and rosuvastatin,, classified in class 514, subclasses 423 and 866.

The four inventions are independent and distinct, each from the other as they have a separate status in the art as shown by their different and separate subject matter for inventive effort. Further, a reference, which anticipates any one of the above inventions, would neither anticipate nor make obvious of the other inventions. Each such invention is capable of supporting is own patent. For these reasons, the restriction requirement is proper.


To be complete, applicants' response must include a provisional election even though the requirement may be traverse.

The applicants are required to elect a single invention for examination purposes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
June 21, 2007